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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/976,423
Filing Date: October 12, 2001
Appellant(s): HOGAN, KIRK

David Casimir
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed November 9, 2005 appealing from the Office action mailed May 10, 2005.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

U.S. Paten application No. 09/613,887, filed July 11, 2000.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

- Applied Biosystems Product Catalog (1993, pages 135-164)

- Perkin Elmer, PCR Systems, Reagents & Consumables (1995-1996, pages 15-18)
- Rosen (US Publication 2002/0119468, August 2002)
- Tarkowski et al. (Neurology, Vol. 54, pages 2077-2081, June 13, 2000)
- Ahern (The Scientist, Vol 9, No. 15, page 20, July 1995)
- In re Ngai, 367 F.3d 1336, 70 U.S.P.Q.2d 1862 (Fed. Cir. 2004)

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

New Matter

1. Claims 72-105 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the amended claims, reference to "a computer program comprising instructions which direct a processor to analyze data derived from use of said reagents" is included. The amendment fails to propose the basis for the new claim. Upon review by the examiner of support for the newly added recitation, the specification does not describe or discuss "a computer program comprising instructions

which direct a processor to analyze data derived from use of said reagents". Instead the specification describes:

> [0186] In some embodiments of the present invention, perioperative genomic profiles are generated using computer-based data analysis of a genetic information sample (e.g., stored nucleic acid sequence information). A sample is collected from a subject at any time (e.g., at birth), sequence information is generated (e.g., through DNA sequencing), and the information is stored (e.g., as digital information on a portable chip). During the perioperative, period, the subject's sequence information is scanned by a computer program for the pre-selected markers. A report (e.g., a perioperative genomic profile) is generated.
>
> [0188] In some embodiments, a computer-based analysis program is used to translate the raw data generated by the genomic profile (e.g., the presence or absence of a given SNP or mutation) into data of predictive value for the clinician (e.g., probability of abnormal pharmacological response, presence of underlying disease, or differential diagnosis of known disease). The clinician (e.g., surgeon or anesthesiologist) can access the predictive data using any suitable means. Thus, in some preferred embodiments, the present invention provides the further benefit that the clinician, who is not likely to be trained in genetics or molecular biology, need not understand the raw data of the genomic profile. The data is presented directly to the clinician in its most useful form. The clinician is then able to immediately utilize the information in order to optimize the perioperative care of the subject.

This description does not support a computer program comprising instructions which direct a processor to analyze data derived from use of said reagents. The specification fails to teach a kit comprising each of these components. There is no disclosure in the instant specification of a kit comprising reagents and a computer program comprising instructions which direct a processor to analyze data derived from use of said reagents. The instant response does not point to any particular location in the specification for support of this kit and these components.

Moreover, the specification in paragraphs 186 and 188 do not particularly teach even a computer program comprising instructions which direct a processor to analyze data derived from use of said reagents. In paragraph 186, there is no description of a computer program comprising instructions which direct a processor to analyze data derived from use of said reagents. This paragraph is directed to scanning information of stored information. There is not teachings of any computer program which comprises instructions to direct analysis of data derived from use of said reagents.

With respect to paragraph 188, there are no teachings of a computer program within a kit. Further, there are no teachings of a computer program comprising instructions which direct a processor to analyze data derived from use of said reagents.

The Claims further require instructions which translate data into recommendations for treatment option (claim 75), a display that can be printed (claim 77), instructions to direct the fate of said data according to the subject's preference (claim 82). None of these limitations are present in the instant application with regard to a computer program comprising instructions. Claim 84 is directed to a computer program comprising instructions which direct a processor to analyze data to indicate an anesthesia treatment course of action. The specification does not appear to teach any computer program comprising instructions to indicate an anesthesia treatment course of action. There are further no instructions to indicate dosages of compounds (claim 92-94), instructions for prophylaxis for thrombosis (claim 95), for example. The response fails to point to any specific support for these computer programs with these instructions in the response.

The concept of "a computer program comprising instructions which direct a processor to analyze data derived from use of said reagents" does not appear to be part of the originally filed invention. Therefore, "a computer program comprising instructions which direct a processor to analyze data derived from use of said reagents" constitutes new matter.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 72-107 are rejected under 35 U.S.C. 102(b) as being anticipated by Applied Biosystems Product Catalog (1993, pages 135-164).

It is noted that these claims contain a preamble which recites an intended use, however, it is also noted that this use does not confer patentable weight on the product claims since the preamble does not materially change what is present in the kit itself and thus represents an intended use of the kit (see MPEP 2111.02). Further, with regard to the limitation that the kits contain instructions for using said kit for generating said perioperative genomic profile for said subject, the inclusion of instructions is not considered to provide a patentable limitation on the claims. See In re Ngai, 367 F.3d

1336, 70 U.S.P.Q.2d 1862 (Fed. Cir. 2004)(holding that an inventor could not patent known kits by simply attaching new set of instructions to that product).

Applied Biosystems provides several products which are packaged for distribution, kits, which allow for detecting the presence of variant alleles of two or more genes. Applied Biosystems products for sale include: a DNA analysis system; software for genetic analysis; electrophoresis accessories including combs, alignment braces, glass plates, manuals; PRISM Ready reaction cycle sequencing kits; AmpliTaq Cycling Sequencing Kits; DNA sequencing Neat reagents Dye primers; activated dyes, template purification kits; etc. Each of these products is capable of detecting the presence of variant alleles of two or more genes. Applied Biosystems teaches numerous computer programs which are sold with the DNA analysis system, for example. Specifically, DNA analysis system- Model 373 is a system which relies upon gel electrophoresis. Sizing, quantitation and sequencing data are automatically generated by GENESCAN or DNA sequence Analysis software. Applied Biosystems uses fluorescence technology for labeling DNA samples and allows products of all four reactions to be run in the same lane. The color-coded data is graphically represented and a corresponding report gives molecular sizes in base pairs and quantity by relative fluorescence amount (page 136). As seen on page 137, col. 1, DNA sequencing and GENESCAN software generate color-coded data with tremendous explanatory power. A tabular report gives band elution time, base pair size, and relative fluorescence amount. Therefore, the computer program associated with the Applied Biosystems system contains instructions which direct a processor to analyze data derived from the use of the labels, gel,

electrophoretic machine, the power supply etc. The system specifically allows for detection of four labels which would enable detection of variant alleles in two or more genes, associated with two or more conditions, as required by the instant claims.

As decided at the Federal Circuit in May 2004, In re Ngai succinctly states that inventors are not "entitled to patent a known product by simply attaching a set of instructions to that product." Whether the instructions are printed on a piece of paper within the kit or the instructions are printed in the memory of the computer for execution, the instructions remain just instructions. With regard to Claims 73-107, the intended use of the instructions written in the memory or program of the computer would not change the product. As in Ngai, the only difference between the Applied Biosystems system and the instant claims is the content of the instructions. Therefore, the different instructions provided in Claims 73-107 do not distinguish over the prior art.

Therefore, since Applied Biosystems teaches every limitation of the claims, Applied Biosystems anticipates the claimed invention.

New Grounds of Rejection

3. Claims 106-107 are rejected under 35 U.S.C. 102(b) as being anticipated by Perkin Elmer, PCR Systems, Reagents & Consumables (1995-1996, pages 15-18).

The instant rejection was originally present at least in the non-final mailed August 24, 2004. The rejection was withdrawn in view of the amendments and arguments to the claims which required a computer. However, as clearly pointed out in the instant response, Claims 106 and 107 do not require a computer.

It is noted that these claims contain a preamble which recites an intended use, however, it is also noted that this use does not confer patentable weight on the product claims since the preamble does not materially change what is present in the kit itself and thus represents an intended use of the kit (see MPEP 2111.02). Further, with regard to the limitation that the kits contain instructions for using said kit for generating said perioperative genomic profile for said subject, the inclusion of instructions is not considered to provide a patentable limitation on the claims because the instructions merely represent a statement of intended use in the form of instructions in a kit. See In re Ngai, 367 F.3d 1336, 70 U.S.P.Q.2d 1862 (Fed. Cir. 2004)(holding that an inventor could not patent known kits by simply attaching new set of instructions to that product).

Perkin Elmer provides several products which are packaged for distribution, kits, which allow for detecting the presence of variant alleles of two or more genes. First, Perkin Elmer teaches the GeneAmp PCR Reagent Kit with AmpliTaq DNA polymerase. The kit contains the components of AmpliTaq DNA polymerase, GeneAmp Buffer, GeneAmp dNTPs, GeneAmp Lambda Control Reagents and package insert with PCR protocols (page 15). This kit provided by Perkin Elmer contains reagents which allow for detection of variant alleles of two or more genes. Perkin Elmer provides several additional variations of the PCR kit (page 16-18). Perkin Elmer specifically teaches that the kits can be used for a wide variety of research application including human genetics, environmental assay, genome mapping and analysis and the study of infections diseases (page 15).

The claims also require "instructions for using said kit for generating said perioperative genomic profile for said subject." Because no patentable weight is given to the written material in the instructions describing a method, the claim is anticipated by Perkin Elmer. As decided at the Federal Circuit in May 2004, In re Ngai succinctly states that inventors are not "entitled to patent a known product by simply attaching a set of instructions to that product."

Therefore, since Perkin Elmer teaches every limitation of the claims, Perkin Elmer anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 106-107 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosen (US Publication 2002/0119468, August 2002) in view of Ahern (The Scientist, Vol 9, No. 15, page 20, July 1995).

The instant rejection was originally present at least in the non-final mailed August 24, 2004. The rejection was withdrawn in view of the amendments to the claims which required a computer. However, as clearly pointed out in the instant response, Claims 106 and 107 do not require a computer.

Rosen teaches methods for identifying a preferred liver transplant donor. Rosen specifically, teaches the genotype of the tumor necrosis factor alpha and beta are analyzed. Rosen specifically takes liver biopsies from patients. Genomic DNA was isolated using a commercial extraction kit from Puregene DNA isolation Kit (a reagent which will detect the presence of variant alleles from two or more genes). Rosen teaches for the TNF-alpha promoter genotyping, a sample of DNA was amplified using PCR primers TNF3431 and TNF 4034 and then sequences using TNF3517 and TNF3966 using an automated sequencer (ABI377 Applied Biosystems). The primers are clearly reagents which allow for the detection of variant alleles, as the sequence configuration at the –308 and –238 positions of the TNF-alpha promoter was determined (para 61). Rosen specifically teaches detecting various alleles from TNF-alpha, either the G or A. Further Rosen teaches genotyping of selected loci of the TNF-alpha and TNF-beta coding regions was performed by PCR amplification and restriction digestion. Rosen teaches that TNF-beta aa13 and aa26 genotyping was performed using mutagenic primers that introduce a restriction enzyme half-site into the PCR product such that discrimination between the two alleles of the polymorphism can be tested with various restriction enzymes. Rosen provides analysis of both the TNF-alpha and beta genotypes and alleles.

Rosen does not specifically teaches packaging necessary reagents into a kit.

However, Ahern teaches reagent kits offer scientists good return on investment. Ahern teaches kits save time and money because the kits already comes prepared.

Ahern teaches kits may comprise instructions that provide researcher detailed instructions to follow.

Therefore, it would have been **prima facie** obvious to one of ordinary skill in the art at the time the invention was made to have modified the teachings of Rosen with the teachings of Ahern to incorporate the necessary reagents into a packaged kit. Rosen specifically teaches two polymorphic genes which are associated with liver transplant donor. Based upon Table 1 and Table 2, the ordinary artisan would have been motivated to have sampled a liver donor for allele 1 in both TNF-alpha and TNF-beta to obtain a liver which is less likely to be rejected. The prior art teaches mutations at –308 and aa13 and aa26 which are associated with predisposition to liver rejection. Thus, the ordinary artisan would have been motivated to have packaged the primers, probes, and reagents of Rosen which are necessary for determining the genotypes of TNF-alpha and beta which are associated with liver donor rejection into a kit, as taught by Ahern for the express purpose of saving time and money.

5. Claims 106-107 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tarkowski et al. (Neurology, Vol. 54, pages 2077-2081, June 13, 2000) in view of Ahern (The Scientist, Vol 9, No. 15, page 20, July 1995).

The instant rejection was originally present at least in the non-final mailed August 24, 2004. The rejection was withdrawn in view of the amendments to the claims which required a computer. However, as clearly pointed out in the instant response, Claims 106 and 107 do not require a computer.

Tarkowski et al. (herein referred to as Tarkowski) teaches TNF gene polymorphisms. Tarkowski teaches analyses of TNFalpha and TNFbeta gene polymorphism. The TNF alpha PCR was constructed and primer sequences were provided which allowed amplification, followed by subsequent digestion with NcoI to determine TNFalpha1 and TNFalpha2 alleles (-308G-A). The TNFbeta primers for amplification and then cleavage were also provided to distinguish the two alleles (+225G-A)(pages 2079). As seen in Figure 1 and 2, the alleles and frequencies in AD patients was provided.

Tarkowski does not specifically teaches packaging necessary reagents into a kit.

However, Ahern teaches reagent kits offer scientists good return on investment. Ahern teaches kits save time and money because the kits already comes prepared. Ahern teaches kits may comprise instructions that provide researcher detailed instructions to follow.

Therefore, it would have been **prima facie** obvious to one of ordinary skill in the art at the time the invention was made to have modified the teachings of Tarkowski with the teachings of Ahern to incorporate the necessary reagents into a packaged kit. Tarkowski specifically teaches two polymorphic genes which are associated with AD. Thus, the ordinary artisan would have been motivated to have packaged the primers, probes, and reagents of Tarkowski which are necessary for determining the genotypes of TNF-alpha and beta which are associated with AD rejection into a kit, as taught by Ahern for the express purpose of saving time and money.

(10) Response to Argument

6. Claims 72-105 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Response to Arguments

`The response traverses the rejection.

Claims 106 and 107 have been withdrawn from the rejection as Appellant correctly pointed out they do not include reference to "a computer program comprising instructions...." Thus, the rejection as it previously applied to Claims 106-107 has been withdrawn.

The response asserts the specification provides full, specific and easily understood support for Claims 72-105. This argument has been thoroughly reviewed, but is not found persuasive because the specification does not teach a kit comprising a computer program comprising instructions which direct a processor to analyze data derived from use of said reagents. The response points to page 40 of the specification, however the passage is directed to an assay for detection of polymorphisms which is computer based data analysis. The specification specifically indicates that protocols and commercially available kits or services are available, indicating the specification is indicating these kits are in the prior art. This does not constitute a kit comprising a

computer program comprising instructions which direct a processor to analyze data derived from use of said reagents.

The response asserts the specification, page 6 supports the invention, however the passage does not discuss a kit comprising a computer program comprising instructions which direct a processor to analyze data derived from use of said reagents. Page 50 of the specification does not discuss kits of any kind. Thus, the specification does not support a kit comprising a computer program comprising instructions which direct a processor to analyze data derived from use of said reagents.

The Appellant sets forth many citations for computer, instructions and processors, however, none of these piecemeal analysis may be combined to obtain a kit comprising a computer program comprising instructions which direct a processor to analyze data derived from use of said reagents.

The Appellant correctly asserts adequate description under 112, first paragraph does not require verbatim support, however the recitation must be conveyed to the ordinary skilled artisan. The instant specification attempts to asserts since each of the words are present in the specification, the concept of a kit comprising a computer program comprising instructions which direct a processor to analyze data derived from use of said reagents was provided. The brief fails to ever provide a passage that supports a computer program in a kit with reagents.

On page 16-20 of the brief the Appellant cites passages from the specification for various dependant claims, however these passages do not support a kit comprising a computer program comprising instructions which direct a processor to analyze data

derived from use of said reagents. While the brief points to numerous passages and numerous recitations of computer programs, none of these computer programs are contemplated in a kit with reagents to detect variant alleles as required by the claims.

7. Claims 72-107 are rejected under 35 U.S.C. 102(b) as being anticipated by Applied Biosystems Product Catalog (1993, pages 135-164).

Response to Arguments

The Appellant traverses the rejection. The Appellant asserts that the prior art does not teach the specific variant allele elements of the present claims because Applied Biosystems does not teach "reagents sufficient to detect the presence or absence of variant alleles" and the reference does not mention the genes recited in the claims (see page 24 of Brief). This argument has been reviewed but is not convincing because the claims recite "reagents which detect the presence of variant alleles of two or more genes..." This limitation does not require any allele specific elements. Reagents which detect the presence of variant alleles encompass any product which may enable detection of variant alleles. The claims do not require probes, primers, but rather reagents. The specification, nor the instant claims, limits reagents to be nucleic acid or more specifically, a nucleic acid flanking, or comprising a variant. As stated above, the instant claims require "reagents which detect the presence of variant alleles of two or more genes..." The claims does not include any recitation with respect to oligonucleotides or more specifically, no recitation of "ASO probes." Rather, the claim broadly encompasses ANY "reagents capable of detecting the presence of variant

alleles of two or more genes..." Therefore, the kit containing a DNA analysis system; software for genetic analysis; electrophoresis accessories including combs, alignment braces, glass plates, manuals; PRISM Ready reaction cycle sequencing kits; AmpliTaq Cycling Sequencing Kits; DNA sequencing Neat reagents Dye primers; activated dyes, template purification kits; etc. meets the limitation of the instant claims. If the sequence is sequenced using the analysis system and the other reagents taught by Applied Biosystems, the ordinary artisan would have determined the presence or absence of a variant allele, for example. The reagents must be "sufficient" to detect a variant in a gene, however, these reagents could be the polymerases that extend nucleic acids, labels which are affixed to nucleic acids, or any other reagent that allows or is sufficient to detect the presence or absence of alleles.

On page 25 of the brief, the Appellant states that the references does not suggest the use of these reagents and components for perioperative applications or for detection of the claimed genes and variant alleles. This argument has been thoroughly reviewed, but is not found persuasive. The MPEP provides in 2112 "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433

(CCPA 1977). Here, the old sequencing products can not be deemed patentable with the new use for the perioperative applications.

With response to the arguments directed to instructions, the Appellant traverses the rejection (pages 27-30, of the Brief). The response argues that "not one of the three prior art references recite the limitation 'instructions for using said kit for generating said perioperative genomic profile for said subject." This argument has been thoroughly reviewed, but is not found persuasive. The examiner previously addressed all of the instant arguments in the Final Office Action of July 8, 2003 and maintains these arguments. Additionally, in view of the recent Federal Circuit case holding that an inventor could not patent known kits simply by attaching new sets of instructions to that product. See In re Ngai, 367 F.3d 1336, 70 U.S.P.Q.2d 1862 (Fed. Cir. 2004). This is the precise issue argued at length by the instant response (pages 30-34). Since the facts and analysis of the instant application and Ngai are analogous, Ngai is deemed the closest authority on the issue of whether printed instructions in a previously disclosed kit makes the kit patentable. In the response filed February 14, 2005, the response asserts that Ngai and the instant application are "diametrically distinct." The response asserts that a kit for generating a perioperative genomic profile for a subject is previously undisclosed product and the instructions are interrelated such that instructions of the purpose of generating a perioperative genomic profile do not achieve their purpose of generating a perioperative genomic profile without the reagents and the reagents of the present invention do not product the desired result without instructions. The response concludes by stating "because the instructions of the present invention

are 1) functionally related to a 2) previously unknown product, the Applicant is entitled to the claims. This argument has been thoroughly reviewed, but is not found persuasive because the kit is not previously unknown. The kit is merely reagents which are sufficient to detect the presence or absence of variant alleles in two or more genes associated with two or more conditions selected from the group consisting of BchE, CYP2D6, F5, F2, CACNAIS, MTHRF, MTR, MTRR, CBS, TNFalpha, and TNFbeta so as to generate a genomic profile. As stated previously on the record, these reagents encompass nearly any reagents. Labels, electrophoresis gels, sequencing machines, enzymes, for example all are regents for detecting variant alleles. Each of these reagents was previously known and placed in a kit for various purposes. While, the kits taught in the art were not specifically for perioperaive genomic profiling, In re Ngai, 367 F.3d 1336, 70 U.S.P.Q.2d 1862 (Fed. Cir. 2004) holds that an inventor could not patent known kits by simply attaching new set of instructions to that product. The instant claims should be no exception to the clearly stated holding of Ngai.

Here the computer comprising instructions for claim 72, for example, which directs a processor to analyze data derived from use of said reagents is literally met by the Applied Biosystems system. With regard to Claims 73-107, the only difference between the claims and the prior art lies in the instructions contained on the computer program.

The Appellant argues that the computer program are functionally related to the kits of the present inventions (see page 33 of Brief). This argument has been thoroughly reviewed, but is not found persuasive because the instructions on the

computer program tell the ordinary artisan what to do with the pieces of the kit. The instructions are not structure.

Moreover, the Declaration of Morris Waxler has been thoroughly considered and deemed not persuasive. The Declaration is specifically designed to establish that instructions for kits, for the purpose of FDA, are considered to be functional by the FDA (see page 34 fo Brief). This argument has been thoroughly reviewed, but is not found persuasive because the standard to patentability does not rely on any requirements made by the FDA. As provided in MPEP 2107.01, for example, it is clear that the requirements for FDA and patent approval should not be confused. Thus, it is clear that the requirements for the FDA approval and for patent approval are not parallel and conclusions regarding FDA requirements are not persuasive or binding on the patent process. The FDA is looking to safety and efficacy and not at the patentability standards of novel, useful and non-obvious. Further, as argued in the February 14, 2005 response, page 14, the response correctly points out that the only reference to the FDA addresses therapeutic utility. It is clear based upon the silence of the MPEP with regard to the FDA on instructions and kits, that the FDA approval process is not considered in the distinct patenting process.

The MPEP 2100 states:

"Nonfunctional descriptive material cannot render nonobvious an invention that would have otherwise been obvious. In re Ngai, **>367 F.3d 1336, 1339, 70 USPQ2d 1862, 1864 (Fed. Cir. 2004) (combining printed instructions and an old product into a kit will not render the claimed invention nonobvious even if the instructions detail a new use for the product).< Cf. In re Gulack, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983) (when descriptive material is not functionally related to the substrate, the descriptive material will not distinguish the invention from the prior art in terms of patentability).

Common situations involving nonfunctional descriptive material are:
- a computer-readable storage medium that differs from the prior art solely with respect to nonfunctional descriptive material, such as music or a literary work, encoded on the medium,
- a computer that differs from the prior art solely with respect to nonfunctional descriptive material that cannot alter how the machine functions (i.e., the descriptive material does not reconfigure the computer), or
-a process that differs from the prior art only with respect to nonfunctional descriptive material that cannot alter how the process steps are to be performed to achieve the utility of the invention.

Thus, if the prior art suggests storing a song on a disk, merely choosing a particular song to store on the disk would be presumed to be well within the level of ordinary skill in the art at the time the invention was made. The difference between the prior art and the claimed invention is simply a rearrangement of nonfunctional descriptive material.

The Brief asserts that computer programs are not printed matter. The brief further asserts that In re Beauregard supports the arguments that the instructions are statutory subject matter. This argument has been thoroughly reviewed, but is not found persuasive because the instant rejection is a 102 rejection and not a non-statutory type rejection. Beauregard states that the computer programs embodied on a tangible mdium must be examined under 102/103. It is noted that the instant computer program is not embodied on a tangible medium, for example as required by Beauregard. Further, as noted above, it is clear from the MPEP that data or instructions on a computer program is deemed to be non-functional descriptive matter. Thus, the examiner relies upon the MPEP and Ngai to support the non-functionality of the "computer program comprising instructions." Instructions that dictate the use of old products whether written on paper or on a computer, would not constitute functional descriptive matter, as suggested by the Appellant. To allow Appellant to "write" their "instructions" on a computer program rather than on a piece of paper would not appear to be in accordance with the substance of the opinion provided in Ngai.

The Appellant provides an example of a hypothetical claim with component Y and component Z wherein compoentnt Z is configured to permit component Y to find use in process X and asserts the patentability. This argument has been thoroughly reviewed, but is not found persuasive. It would seem given the MPEP 2112 "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999); this system would not meet the standards set forth under 102 if the prior art teaches a system with component Y and Z.

With respect to the arguments (page 16-17) of the response filed on June 30, 2004 and February 14, 2005, the response argues that "physically or chemically affect the chemical nature" and "uses for other purpose" is not the law. This argument has been thoroughly reviewed, but is not found persuasive because it is clear from the decision of Ngai that since the known products are not changed, the inventor can not patent known kits simply by attaching new set of instructions to that product."

Thus for the reasons above and those already of record, the rejection is maintained.

8. Claims 106-107 are rejected under 35 U.S.C. 102(b) as being anticipated by Perkin Elmer, PCR Systems, Reagents & Consumables (1995-1996, pages 15-18).

Response to Arguments

The response traverses the rejection. The response asserts that the prior art does not teach the specific variant allele elements of the present claims. This argument has been reviewed but is not convincing because the claims recite "reagents which detect the presence of variant alleles of two or more genes..." This limitation does not require any allele specific elements. Reagents which detect the presence of variant alleles encompass any product which may enable detection of variant alleles. The specification, nor the instant claims, limits reagents to be nucleic acid or more specifically, a nucleic acid flanking, or comprising a variant. As stated above, the instant claims require "reagents which detect the presence of variant alleles of two or more genes..." The claims does not include any recitation with respect to oligonucleotides or more specifically, no recitation of "ASO probes." Rather, the claim broadly encompasses ANY "reagents capable of detecting the presence of variant alleles of two or more genes..." Therefore, the kit containing the components of AmpliTaq DNA polymerase, GeneAmp Buffer, GeneAmp dNTPs, GeneAmp Lambda Control Reagents and package insert with PCR protocols meets the limitation of the instant claims.

With response to the arguments directed to instructions, the response traverses the rejection (page 12, of response filed June 3, 2004. The response argues that "not one of the three prior art references recite the limitation 'instructions for using said kit for generating said perioperative genomic profile for said subject." This argument has been thoroughly reviewed, but is not found persuasive. The examiner previously addressed all of the instant arguments in the Final Office Action of July 8, 2003 and maintains

these arguments. Additionally, in view of the recent Federal Circuit case holding that an inventor could not patent known kits simply by attaching new sets of instructions to that product. See In re Ngai, 367 F.3d 1336, 70 U.S.P.Q.2d 1862 (Fed. Cir. 2004). This is the precise issue argued at length by the instant response (pages 12-18). Since the facts and analysis of the instant application and Ngai are the same, Ngai is deemed the closest authority on the issue of whether printed instructions in a previously disclosed kit makes the kit patentable.

Moreover, the Declaration of Morris Waxler has been thoroughly considered and deemed not persuasive. The Declaration is specifically designed to establish that instructions for kits, for the purpose of FDA, are considered to be functional by the FDA. This argument has been thoroughly reviewed, but is not found persuasive because the standard to patentability does not rely on any requirements made by the FDA. As provided in MPEP 2107.01, for example, it is clear that the requirements for FDA and patent approval should not be confused. Thus, it is clear that the requirements for the FDA approval and for patent approval are not parallel and conclusions regarding FDA requirements are not persuasive or binding on the patent process.

With respect to the arguments (page 20-22) of the response filed on June 30, 2004, the response argues that "physically or chemically affect the chemical nature" and "uses for other purpose" is not the law. This argument has been thoroughly reviewed, but is not found persuasive because it is clear from the decision of Ngai that since the known products are not changed, the inventor can not patent known kits simply by attaching new set of instructions to that product."

Thus for the reasons above and those already of record, the rejection is maintained.

9. Claims 106-107 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosen (US Publication 2002/0119468, August 2002) in view of Ahern (The Scientist, Vol 9, No. 15, page 20, July 1995).

Response to Arguments

The response traverses the rejection. The response asserts that the combination of references does not teach all elements of the claims (see page 19 of response file by Appellant February 17, 2005). This argument has been thoroughly reviewed, but is not found persuasive because the elements of the claims require reagents sufficient to detect variant alleles from TNFalpha and TNFbeta. These two genes are inherently associated with two or more conditions. The claims are drawn to products, not methods, therefore, the products of Rosen would inherently meet the limitations of the instant claims. Rosen specifically teaches genotyping of selected loci of the TNF-alpha and TNF-beta loci using reagents. As argued above, placing these reagents in a kit would have been obvious at the time the invention was made.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re*

Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Ahern teaches kits save time and money because the kits already comes prepared. Ahern teaches kits may comprise instructions that provide researcher detailed instructions to follow. Therefore, to place reagents for carrying out a method into a kit would have been obvious at the time the invention was made.

10. Claims 106-107 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tarkowski et al. (Neurology, Vol. 54, pages 2077-2081, June 13, 2000) in view of Ahern (The Scientist, Vol 9, No. 15, page 20, July 1995).

Response to Arguments

The response traverses the rejection. The response asserts that the combination of references does not teach all elements of the claims (see page 19 of response file by Appellant February 17, 2005). This argument has been thoroughly reviewed, but is not found persuasive because the elements of the claims require reagents sufficient to detect variant alleles from TNFalpha and TNFbeta. These two genes are inherently associated with two or more conditions. The claims are drawn to products, not methods, therefore, the products of Tarkowski would inherently meet the limitations of the instant claims. Tarkowski specifically teaches genotyping of selected loci of the TNF-alpha and TNF-beta loci using reagents. As argued above, placing these reagents in a kit would have been obvious at the time the invention was made.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by

combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Ahern teaches kits save time and money because the kits already comes prepared. Ahern teaches kits may comprise instructions that provide researcher detailed instructions to follow. Therefore, to place reagents for carrying out a method into a kit would have been obvious at the time the invention was made.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

This examiner's answer contains a new ground of rejection set forth in section **(9)** above. Accordingly, appellant must within **TWO MONTHS** from the date of this answer exercise one of the following two options to avoid *sua sponte* **dismissal of the appeal** as to the claims subject to the new ground of rejection:

(1) **Reopen prosecution.** Request that prosecution be reopened before the primary examiner by filing a reply under 37 CFR 1.111 with or without amendment,

affidavit or other evidence. Any amendment, affidavit or other evidence must be relevant to the new grounds of rejection. A request that complies with 37 CFR 41.39(b)(1) will be entered and considered. Any request that prosecution be reopened will be treated as a request to withdraw the appeal.

(2) **Maintain appeal.** Request that the appeal be maintained by filing a reply brief as set forth in 37 CFR 41.41. Such a reply brief must address each new ground of rejection as set forth in 37 CFR 41.37(c)(1)(vii) and should be in compliance with the other requirements of 37 CFR 41.37(c). If a reply brief filed pursuant to 37 CFR 41.39(b)(2) is accompanied by any amendment, affidavit or other evidence, it shall be treated as a request that prosecution be reopened before the primary examiner under 37 CFR 41.39(b)(1).

Extensions of time under 37 CFR 1.136(a) are not applicable to the TWO MONTH time period set forth above. See 37 CFR 1.136(b) for extensions of time to reply for patent applications and 37 CFR 1.550(c) for extensions of time to reply for ex parte reexamination proceedings.

Respectfully submitted,

Jeanine Goldberg
Primary Examiner

JEANINE A. GOLDBERG
PRIMARY EXAMINER
12/19/05

A Technology Center Director or designee must personally approve the new ground(s) of rejection set forth in section (9) above by signing below:

Jasmine Chambers
Group Director 1600

JASEMINE C. CHAMBERS
DIRECTOR
TECHNOLOGY CENTER 1600

Conferees:

Gary Jones
Supervisory Patent Examiner

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600

Remy Yucel
Supervisory Patent Examiner

REMY YUCEL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600